DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 2, 2016

DePuy Orthopaedics
Ms. Megan Burns
Associate, Regulatory Affairs
700 Orthopaedic Drive
Warsaw, Indiana 46580

Re: K120174
Trade/Device Name: DePuy Delta XTend™ Reverse Shoulder System
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWS, HSD
Dated: May 11, 2012
Received: May 14, 2012

Dear Ms. Burns:

This letter corrects our substantially equivalent letter of June 11, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4: Indications for Use Statement

510(k) Number (if known): ~~K012174~~ K120174

Device Name: DePuy Delta Xtend™ Reverse Shoulder System

INDICATIONS FOR USE:
The Delta Xtend Shoulder Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with:

- severe arthropathy and/or;
- a previously failed joint replacement and/or:
- fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory

The patient's joint must be anatomically and structurally suited to receive the selected implant(s), and a functional deltoid muscle is necessary to use the device.

Delta Xtend hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for the revision of a previously failed Delta Xtend Reverse Shoulder.

The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation.

The modular humeral stem and humeral epiphysis components are HA coated and intended for cementless use.

All other metallic components are intended for cemented use only.

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K120174

Prescription Use X
(Part 21 CFR 801 Subpart D)

~~Over-The-Counter~~ Use _____
(Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K120174

JUN 1 1 2012

Section 5: 510(k) Summary

(as required by 21 CFR 807.92)

Submitter Information	
Name:	DePuy Orthopaedics
Address:	700 Orthopedic Drive
Phone number:	574-372-7745
Fax number:	574- 371-4987
Establishment Registration:	1818910
Name of contact person:	Megan Burns
Date prepared:	9 May 2012
Device Information	
Trade or proprietary name:	**DePuy Delta Xtend™ Reverse Shoulder System**
Common or usual name:	Shoulder Prosthesis
Class:	II
Classification name:	21 CFR 888.3660: Prosthesis, shoulder, semi-constrained, metal/polymer cemented Class II Device per 21 CFR 888.3690: Prosthesis, Shoulder, Hemi, Humeral, Metallic, Uncemented
Classification panel:	Orthopedics
Regulation:	21 CFR 888.3660: Shoulder joint metal/polymer semi-constrained cemented prosthesis 21 CFR 888.3690: Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis
Product Code(s):	KWS, HSD
Legally marketed device(s) to which equivalence is claimed:	DePuy Delta Xtend™ Reverse Shoulder System. K062250 Comprehensive® Reverse Shoulder, K080642 Aequalis® Reversed Fracture Shoulder Prosthesis, K082120
Reason for 510(k) submission:	Line extension and additional indication
Device description:	The DePuy Delta Xtend™ Reverse Shoulder System is a total shoulder prosthesis that consists of monobloc and modular humeral stems, humeral cup, humeral head, humeral spacer, glenosphere, metaglene and metaglene screws.
Intended Use:	The DePuy Delta Xtend™ Reverse Shoulder Prosthesis is intended for use in total shoulder or hemi-shoulder replacement procedures in patients with non-functional rotator cuffs, with or without bone cement. HA-coated components are for cementless use only.

Device Information, continued:	
Indications for use:	The Delta Xtend Shoulder Prosthesis is indicated for use in treatment of a grossly deficient rotator cuff joint with: • severe arthropathy and/or; • a previously failed joint replacement and/or; • fracture-dislocations of the proximal humerus where the articular surface is severely comminuted, separated from its blood supply or where the surgeon's experience indicates that alternative methods of treatment are unsatisfactory The patient's joint must be anatomically and structurally suited to receive the selected implant(s). and a functional deltoid muscle is necessary to use the device. Delta Xtend hemi-shoulder replacement is also indicated for hemi-arthroplasty if the glenoid is fractured intraoperatively or for the revision of a previously failed Delta Xtend Reverse Shoulder. The metaglene component is HA coated and is intended for cementless use with the addition of screws for fixation. The modular humeral stem and humeral epiphysis components are HA coated and intended for cementless use. All other metallic components are intended for cemented use only.

Summary of the technological characteristics of the device compared to the predicate device				
CHARACTERISTIC	**Subject Device: Delta Xtend™ Reverse Shoulder (Long Peg Metaglene & Fracture Indication)**	**Metaglene Predicate Device: Delta Xtend™ Reverse Shoulder (DEPUY) K062250**	**Fracture Predicate Device: *Aequalis Reversed Fracture* (TORNIER) K082120**	**Fracture Predicate Device: *Comprehensive Reverse* (BIOMET) K080642**
Shoulder System	• Reverse articulation, modular humeral implant & monobloc humeral implant	• Reverse articulation, modular humeral implant & monobloc humeral implant	• Reverse articulation, monobloc humeral implant	• Reverse articulation, modular humeral implant
Intended Use	• Total or hemi shoulder arthroplasty	• Same	• Same	• Same
Summary of the technological characteristics, continued:				
CHARACTERISTIC	**Subject Device: Delta Xtend™ Reverse Shoulder (Long Peg Metaglene & Fracture Indication)**	**Metaglene Predicate Device: Delta Xtend™ Reverse Shoulder (DEPUY) K062250**	**Fracture Predicate Device: *Aequalis Reversed Fracture* (TORNIER) K082120**	**Fracture Predicate Device: *Comprehensive Reverse* (BIOMET) K080642**

Components				
	• CoCr Monobloc stem and epiphysis • Titanium modular epiphysis with HA coating • Titanium modular stem with HA coating • Titanium metalback standard metaglene with HA coating • Titanium metalback long peg metaglene with HA coating (new components) • Titanium screws • CoCr hemispherical glenosphere component • Ultra-high Molecular Weight Polyethylene (UHMWPE) or Premieron™ X-Linked Polyethylene cups • Titanium humeral spacer	• CoCr Monobloc stem and epiphysis • Titanium modular epiphysis with HA coating • Titanium modular stem with HA coating • Titanium metalback standard metaglene with HA coating • Titanium screws • CoCr hemispherical glenosphere component • Ultra-high Molecular Weight Polyethylene (UHMWPE) or Premieron™ X-Linked Polyethylene cups • Titanium humeral spacer	• Titanium alloy Monobloc stem and epiphysis • Titanium metalback standard metaglene with HA coating • Titanium metalback long peg Metaglene with HA coating • Titanium alloy screws • Cobalt Chromium hemispherical glenosphere component • Ultra-high Molecular Weight Polyethylene (UHMWPE) cups • CoCr alloy humeral spacer	• Titanium alloy Monobloc stem and epiphysis • Titanium modular epiphysis plate • Titanium modular distal stem • Titanium metalback standard metaglene with porous coating • Titanium screws • Cobalt Chromium hemispherical glenosphere component • Ultra-high Molecular Weight Polyethylene (UHMWPE) cups
Fixation				
Bone cement	Cemented/cementless	Same	Cemented only	Same
Suture Holes	Yes	Yes	Yes	Yes

PERFORMANCE DATA

SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE

Performance Test Summary-New Device

Characteristic	Standard/Test/FDA Guidance	Results Summary
A stack analysis of the subject and predicate metaglene devices concluded the components to be equivalent in design except in peg length. The analysis also concluded the subject metaglene device to be compatible with the existing glenosphere.		

Comparative Performance Information Summary

Characteristic	Requirement	New Device	Predicate Device
No non-clinical testing was required to demonstrate substantial equivalence.			

SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION

No clinical tests were conducted to demonstrate substantial equivalence.

CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA

The results of the non-clinical testing demonstrate substantial equivalence to the predicate.